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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/692,338

10/23/2003

Terri L. Butler

BP. 028 US2

8488

46350

7590

02/26/2007

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EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT

PAPER NUMBER

1623

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/26/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/692,338	<b>Applicant(s)</b> BUTLER ET AL.	
	<b>Examiner</b> Traviss C. McIntosh	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1- 3 and 6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National-Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The Amendment filed November 20, 2006 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 1 and 6 have been amended.

Claims 4-5 and 7-17 have been canceled.

Remarks drawn to rejections of Office Action mailed June 16, 2006 include:

Specification objections: which have been overcome by applicant's amendments and have been withdrawn.

Claim objections: which have been overcome by applicant's amendments and have been withdrawn.

Double Patenting rejections: which have been overcome in part by the filing of a terminal disclaimer over US 6,218,366 and maintained in respect to application 11/118,613.

112 1<sup>st</sup> paragraph rejections regarding "consisting of" has been withdrawn due to applicants arguments.

103(a) rejections: which have been overcome by applicant's amendments and arguments have been withdrawn.

An action on the merits of claims 1-3 and 6 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

*Double Patenting*

The rejection of claims 1-3 and 6 as being provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-5 of copending Application No. 11/118,613 is being maintained for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to treating vascular conditions using the same therapy. It is noted that the instant application is drawn to improving cardiovascular function in a subject with congestive heart failure and the '613 application is drawn to methods of improving ventilatory efficiency in a subject having reduced ventilatory efficiency, however, CHF is known to occur when the flow of blood from the heart decreases, or fluid backs up in the failing ventricle, or both. and thus increasing the blood flow from the heart would also be seen to improve ventilatory efficiency, as ventilatory efficiency is the rate at which CO<sub>2</sub> is removed from the body, thus dependent on the output rate of the heart. Thus, a subject having CHF, as in the instant application, is seen to be a subject that has reduced ventilatory efficiency as in the '613 patent. One of skill in the art would find it obvious that these applications are substantially overlapping in the subject matter that they are claiming.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants argue that the instant application has an earlier priority date, and that the '613 application is not available as a reference. The examiner notes that while the '613 application does have a later filing date, it is of no patentable import in the instant rejection, as all that is

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required for the instant rejection to be made is the applications be copending. See chart I-b in MPEP 804[R5] . This rejection is maintained for the reasons set forth above.

***Claim Rejections - 35 USC § 112***

Claims 1-3 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is noted that in the amendment filed on 1/20/2004, applicants amended the claims to include the phrase “chronic administration”. However, it is noted that applicants did not have support for the newly claimed range. Applicants do not define the term “chronic administration” in their specification, and one of skill in the art would not know the meaning of the phrase. The changing of the scope of a claim, either by broadening or narrowing, can be construed as new matter as either is capable of changing the scope of what is claimed, and the narrower or broader group must be supported in its entirety by the specification as originally filed. It is noted that the word “chronic” as set forth by the definition in Wikipedia states that:

“In medicine, a **chronic disease** is a disease that is long-lasting or recurrent. The term *chronic* describes the course of the disease, or its rate of onset and development. A chronic course is distinguished from a recurrent course; recurrent diseases relapse repeatedly, with periods of remission in between. As an adjective, *chronic* can refer to a persistent and lasting medical condition. *Chronicity* is usually applied to a condition that lasts more than three months.

The definition of a disease or causative condition may depend on the disease being chronic, and the term will often appear (in) the description”.

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As such, the term "chronic administration" is seen to be indefinite as one of skill in the art would not know what the term "chronic administration" was meant to intend.

Claims 2-3 are indefinite wherein the claims provide additional agents to be included in the composition used in claim 1, however, claim 1 as amended uses closed language, i.e. "Consisting of", and as such, it is improper to then add additional agents into a composition which is intended not to have anything added thereto. Changing the dependent claims to independent claims, with all of the limitations of the previous claims, would be seen to overcome the instant rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

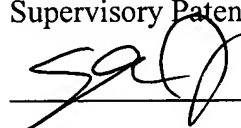
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss McIntosh  
February 20, 2007

Shaojia A. Jiang  
Art Unit 1623  
Supervisory Patent Examiner

 2/20/07